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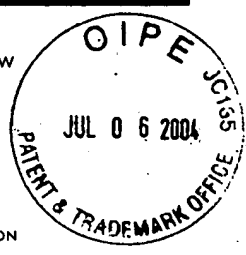
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AND RELATED MATTERS



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(1938-1999)

June 30, 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/731,041 filed December 8, 2003  
Applicant: Steven W. Sanders, et al.  
Title: **COMPOSITIONS AND METHODS FOR MINIMIZING ADVERSE  
DRUG EXPERIENCES ASSOCIATED WITH OXYBUTYNNIN  
THERAPY**  
Group Art Unit: 1613  
Attorney Docket No. T7770.CON3

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is an Information Disclosure Statement.

Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- ☒ Form PTO-1449 list of 55 references submitted for consideration.
- ☐ Legible copies of the listed references or their relevant portions.
- ☐ Legible copies of the listed non-patent documents and foreign documents or their relevant portions are included.
- ☒ Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).

- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- ☒ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application no. 10/098,752, filed on March 15, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☐ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☐ Check No. \_\_\_\_\_, which includes the amount of \$0.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

Respectfully submitted,

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Enc.



IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1613

EXAMINER:

APPLICANT: Steven W. Sanders, et al.

SERIAL NO.: 10/731,041

FILED: 12/8/2003

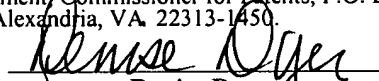
CONFRM. NO.: 7569

FOR: COMPOSITIONS AND METHODS FOR  
MINIMIZING ADVERSE DRUG  
EXPERIENCES ASSOCIATED WITH  
OXYBUTYNIN THERAPY

**CERTIFICATE OF MAILING  
UNDER 37 C.F.R. § 1.8**

DATE OF DEPOSIT: 7/2/04

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Denise Dyer

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

☒ 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;

☐ 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in § 1.17(p); or

☐ 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in § 1.17(p).

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☐ In accordance with 37 C.F.R. §§ 1.97 and 1.98, a copy of each listed reference (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is also enclosed.

☒ Copies of U.S. patents and/or publications are NOT included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).

☒ The articles listed in the accompanying Form PTO-1449 are NOT enclosed because, under 37 C.F.R. § 1.98(d), they were previously cited by or submitted to the Office in application number 10/098,752, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

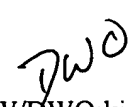
Dated this 2nd day of July, 2004.

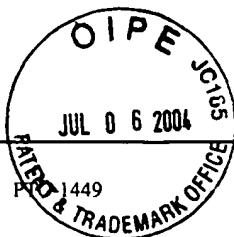
Respectfully submitted,



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Enclosure



<b>LIST OF PRIOR ART CITED BY APPLICANT</b>	<b>U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE</b>	<b>ATTY. DOCKET NO.</b> T7770.CON3	<b>SERIAL NO.</b> 10/731,041
	<b>APPLICANT</b> Steven W. Sanders, et al.		
	<b>FILING DATE</b> Dec. 8, 2003		<b>GROUP</b> 1613

**U.S. PATENT DOCUMENTS**

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	4,652,441	3/24/87	Okada, et al.			
	A2	4,959,217	9/25/90	Sanders, et al.			
	A3	5,028,430	7/2/91	Sanders, et al.			
	A4	5,152,997	10/6/92	Ebert, et al.			
	A5	5,164,190	11/17/92	Patel, et al.			
	A6	5,212,199	5/18/93	Heiber, et al.			
	A7	5,227,169	7/13/93	Heiber, et al.			
	A8	5,411,740	5/2/95	Lee, et al.			
	A9	5,500,222	3/19/96	Lee, et al.			
	A10	5,516,808	5/14/96	Sawaya			
	A11	5,532,278	7/2/96	Aberg, et al.			
	A12	5,575,987	11/19/96	Kamei, et al.			
	A13	5,582,838	12/10/96	Rork, et al.			
	A14	5,601,839	2/11/97	Quan, et al.			
	A15	5,614,211	3/25/97	Gale, et al.			
	A16	5,626,866	5/6/97	Ebert, et al.			
	A17	5,641,504	6/24/97	Lee, et al.			
	A18	5,643,584	7/1/97	Farng, et al.			
	A19	5,674,895	10/7/97	Guittard, et al.			
	A20	5,677,346	10/14/97	Aberg, et al.			
	A21	5,721,275	2/24/98	Bazzano			
	A22	5,736,577	4/7/98	Aberg, et al.			
	A23	5,747,065	5/5/98	Lee, et al.			
	A24	5,759,583	6/2/98	Iwamoto, et al.			
	A25	5,762,953	6/9/98	Venkateshwaran			
	A26	5,783,208	7/21/98	Venkateshwaran, et al.			
	A27	5,840,754	11/24/98	Guittard, et al.			
	A28	5,862,555	1/26/99	Furuhashi			

PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. T7770.CON3	SERIAL NO. 10/731,041
LIST OF PRIOR ART CITED BY APPLICANT		APPLICANT Steven W. Sanders, et al.	
		FILING DATE December 8, 2003	GROUP 1613

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A29	5,891,462	4/6/99	Carrara			
	A30	5,891,920	4/6/99	Hirano, et al.			
	A31	5,900,250	5/4/99	Lee, et al.			
	A32	5,912,268	6/15/99	Guittard, et al.			
	A33	5,922,342	7/13/99	Shah, et al.			
	A34	5,939,094	8/17/99	Durif, et al.			
	A35	5,948,433	9/7/99	Burton, et al.			
	A36	5,972,369	10/26/99	Roorda, et al.			
	A37	5,985,305	11/16/99	Perry, et al.			
	A38	5,985,317	11/16/99	Venkateshwaran, et al.			
	A39	6,096,339	8/1/2000	Ayer, et al.			
	A40	6,187,323	2/13/01	Aiache, et al.			
	A41	6,203,817	3/20/01	Cormier, et al.			
	A42	6,258,830	7/10/01	Charu			
	A43	6,319,913	11/20/01	Mak, et al.			
	A44	Pub. No. 0147236A1	10/10/02	Sanders, et al.			
	A45	Pub. No. 0031787A1	10/18/01	Hsu, et al.			
	A46	Pub. No. 0161044A1	10/31/02	Sherratt, et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	A47	WO 99/48494	9/30/99				
	A48	WO 92/10231	6/25/92				
	A49	WO 92/20377	11/26/92				
	A50	WO 93/23025	11/25/93				
	A51	WO 95/09007	4/6/95				

PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. T7770.CON3	SERIAL NO. 10/731,041
		APPLICANT Steven W. Sanders, et al.	
		FILING DATE December 8, 2003	GROUP 1613

**LIST OF PRIOR ART CITED BY APPLICANT**

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	A52	WO 99/48493	9/30/99				

**OTHER PRIOR ART (Including Author, Title, Pertinent Pages, Etc.)**

	A53	L. NORONHA-BLOB and J. F. KACHUR, <i>Enantiomers of Oxybutynin: In Vitro Pharmacological Characterization at M<sub>1</sub>, M<sub>2</sub> and M<sub>3</sub> Muscarinic Receptors and in Vivo Effects on Urinary Bladder Contraction, Mydriasis and Salivary Secretion in Guinea Pigs</i> , Journal of Pharmacology and Experimental Therapeutics, 256: 562-567, (1990).
	A54	ERNEST W. MERRITT and EUGENE R. COOPER, <i>Diffusion Apparatus for Skin Penetration</i> , Journal of Controlled Release, 1: 161-162, (1984).
	A55	JAMES F. KACHUR, JAN S. PETERSON, J. PAUL CARTER, W. JANUSZ RZESZOTARSKI, ROBERT C. HANSON and LALITA NORONHA-BLOB, <i>R and S Enantiomers of Oxybutynin: Pharmacological Effects in Guinea Pig Bladder and Intestine</i> , The Journal of Pharmacology and Experimental Therapeutics, 247: 3, 867-872, (1988).
EXAMINER		DATE CONSIDERED

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.